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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 839,136	04 23 2001	Naoyuki Taniguchi	02356 7	2908

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KENYON & KENYON  
1500 K STREET, N.W., SUITE 700  
WASHINGTON, DC 20005

EXAMINER
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RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/839,136	TANIGUCHI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Manjunath N Rao, Ph.D.	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 May 2003.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 27-37 is/are pending in the application.

4a) Of the above claim(s) 30-34, 36 and 37 is/are withdrawn from consideration.

5) Claim(s) 35 is/are allowed.

6) Claim(s) 27-29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

Claims 27-37 are still pending in this application. Claims 27-29 and 35 are now under consideration. Claims 30-34 and 36-37 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 5-2-03 paper No.10, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### *Specification*

The amendment/sequence listing filed 10-23-01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Examiner has found that applicants have changed the amino acid at position 65 in SEQ ID NO:2 from "glutamic acid (E)" to "Glycine (G)" (see enclosed sequence alignments comparing SEQ ID NO:2 in parent applications and instant application).

Applicant is required to cancel the new matter in the reply to this Office Action.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Uozumi (a) et al. (Biochemistry, 1995, Vol. 67(7):abstr. no.4053, recited in the IDS) or rejected under 35 U.S.C. 102(a) as being anticipated by Uozumi (b) et al. (J. Biol. Chem., Nov. 1996, Vol. 271(44):27810-27817 recited in IDS). This rejection is based upon the public availability of a printed publication and as the invention was known or used by others in this country, or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. Claims 27-28 of the instant application are drawn to an isolated porcine  $\alpha$  1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of 4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000 and is purified from porcine brain. Uozumi et al. disclose an identical  $\alpha$  1,6-fucosyltransferase isolated from pig brain. Therefore, Uozumi et al. anticipate claims 27-28 of this application as written. Examiner would like to point out to the applicants that he had inadvertently indicated the above rejection using the reference of Uozumi (a) et al. as under 35 U.S.C. 102(a) as opposed to being rejected under 35 U.S.C. 102(b).

In response to the previous Office action, applicants have traversed the above rejection arguing that the reference mentions but does not teach the purification of the  $\alpha$  1-6

fucosyltransferase and that the reference therefore is not enabled. Applicants also argue that the reference does not sufficiently teach experimental conditions including buffers etc. sufficient to make and use the claimed invention. Examiner respectfully disagrees with such an argument as being persuasive to overcome the above rejection. Contrary to applicants argument using the information provided in the abstract, it would be well within the knowledge of those skilled in the art to arrive at the instant invention. Furthermore, instant claims are not limited to the arguments that applicants provide to overcome the above rejection. Therefore, Examiner continues to maintain the above rejection.

Examiner has withdrawn the rejection of claim 27 under 35 U.S.C. 102(b) as being anticipated by Longmore et al. (Carbohydrate Res., 1982, Vol. 100 :365-392) in view of the clear differences pointed out by the applicants (i.e., sensitivity to divalent cat ions) between the instant enzyme and the enzyme in the reference.

Claims 27-29, 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Uozumi (b) et al. (J. Biol. Chem., Nov. 1996, Vol. 271(44):27810-27817 recited in IDS). This rejection is based upon the public availability of a printed publication and as the invention was known or used by others in this country, or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. Claims 27-29, 35 of the instant application are drawn to an isolated porcine  $\alpha$  1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of

4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000 and is purified from porcine brain, a recombinantly produced said enzyme wherein the recombinant enzyme is produced by culturing a transformant transformed with a vector comprising the polynucleotide with SEQ ID NO:1 or a polynucleotide encoding the amino acid sequence SEQ ID NO:2 followed by harvesting the expressed enzyme. Uozumi et al. disclose an identical  $\alpha$  1,6-fucosyltransferase isolated from pig brain (see sequence alignment, with Accession No. P79282, except for one single mismatch at position 65 which appears as a new matter in the instant application but not seen in the parent applications) as the enzyme having 100% sequence match with SEQ ID NO:2. the reference also discloses the recombinant form of the enzyme produced by culturing a transformant transformed with a vector comprising the polynucleotide encoding the amino acid sequence, SEQ ID NO:2, followed by harvesting the expressed enzyme. Therefore, Uozumi et al. anticipate claims 27-29, 35 of this application as written.

Examiner has withdrawn the previous obviousness rejection and replaced with the above rejection. Therefore applicants arguments to overcome that rejection is moot.

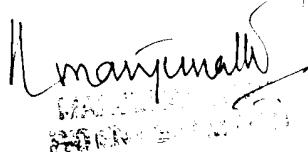
### ***Conclusion***

None of the claims are allowable.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao  
June 26, 2003